HUMAN SUBJECTS RESEARCH
"SECTION E"

Grant Application Face Page

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY.

Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☐ YES
(If "Yes," state number and title)
Number: Title:

3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR	New Investigator ☐ No ☐ Yes	
3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. eRA Commons User Name
3c. POSITION TITLE	3d. MAILING ADDRESS *(Street, city, state, zip code)*	
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT		
3f. MAJOR SUBDIVISION		
3g. TELEPHONE AND FAX *(Area code, number and extension)* TEL: FAX:	E-MAIL ADDRESS:	

4. HUMAN SUBJECTS RESEARCH ☐ No ☒ Yes	4b. Human Subjects Assurance No. Put your FWA number here		5. VERTEBRATE ANIMALS ☐ No ☐ Yes	
	4c. Clinical Trial ☐ No ☒ Yes	4d. NIH-defined Phase III Clinical Trial ☐ No ☒ Yes	5a. If "Yes," IACUC approval Date	5b. Animal welfare assurance no.
4a. Research Exempt ☒ No ☐ Yes	If "Yes," Exemption No. NA		NA	NA

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)

9. APPLICANT ORGANIZATION 10. TYPE OF ORGANIZATION

Human Subjects Assurance Number

- If your institution is engaged in human subjects research that is conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS), then your institution must have an OHRP-approved assurance of compliance with the HHS regulations (45 CFR 46.103) for the protection of human subjects.

A Two-Step Process

- Obtaining an approved assurance from OHRP is a two-step process. First, you must ensure that the IRB(s) you designate under the Assurance are registered with OHRP. If not, submit the registration. Second, you must complete the Assurance application.

OHRP Mission

- http://www.hhs.gov/ohrp/
- The Office for Human Research Protections (OHRP) provides leadership and oversight on all matters related to the protection of human subjects participating in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure that such research is carried out in accordance with the highest ethical standards and in an environment where all who are involved in the conduct or oversight of human subjects research understand their primary responsibility for protecting the rights, welfare, and well-being of subjects.

OHRP International Activities

- OHRP provides quality improvement consultation and research ethics training to domestic and foreign institutions involved in international biomedical and behavioral research to help ensure that recognized ethical protections are afforded to persons participating in research conducted in countries outside the United States.

Human Subjects Research

- **Clinical Trials <u>Unit</u> Responsibilities:**
- Activities at each Site
- Research conducted under US and host country regulations
- Active IRB registered with DHHS
- Federalwide Assurance (FWA)
- Community Advisory Board (CAB) structure and support

Human Subjects Research

- **Clinical Trials Site Responsibilities:**
- Infrastructure for clinical trials
  - Characterized participant cohort
  - Processes in place for adherence to Good Clinical Practice (GCP)
- Institutional support
- Active IRB registered with DHHS
- Federal Wide Assurance (FWA)
- Community Advisory Board (CAB) structure and support

- In the Human Subjects Research section of the Research Plan, you must provide sufficient information for reviewers to determine that the proposed research meets the requirements of the HHS regulations to protect human subjects from research risks and the requirements of NIH policies on inclusion of women, minorities, and children.

- For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children, based on the information in the application.

Human Subjects Research

- **PHS 398 Section E. Human Subjects Research**

- Protection of Human Subjects
- Data and Safety Monitoring Plan
- Inclusion of Women and Minorities
  - Include Targeted/Planned Enrollment Table
- Inclusion of Children

PROTECTION OF HUMAN SUBJECTS

(not part of 10-page limit)

- RISKS TO THE SUBJECTS
  - -Describe human subjects involvement and characteristics
  - -Identify criteria for inclusion or exclusion of any subpopulation
  - -Describe sources of human subject materials (specimens, records)
  - -Describe and assess the likelihood and seriousness of potential risks to subjects

- ADEQUACY OF PROTECTION AGAINST RISKS
  - -Describe plans for the recruitment of subjects and the process for obtaining informed consent
  - -Describe planned procedures for protecting against or minimizing potential risks

- DISCUSS POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS, AND THE IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

Human Subjects Research

- DATA SAFETY AND MONITORING PLAN
- REQUIREMENTS FOR NIH PHASE III TRIALS
- **ARE NOT REQUIRED IN UNIT APPLICATION OR SITE DESCRIPTION**

Human Subjects Research

INCLUSION OF WOMEN AND MINORITIES

(DOMESTIC SITES)

- Participants in trials must be representative of populations most impacted by HIV/AIDS within their geographic region
- Particular consideration given to gender and minority groups
- Include Targeted/Planned Enrollment Table

- (See RFA pages 20,27 and PHS 398 Supplemental Instructions for HS pages 15-19)

Human Subjects Research

INCLUSION OF WOMEN AND MINORITIES

(INTERNATIONAL SITES)

- Include Targeted/Planned Enrollment Table
- (See RFA page 20 and PHS 398 Supplemental Instructions for HS pages 15-19)

Human Subjects Research

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: _____

Total Enrollment: _____ **Protocol Number:** _____

Grant Number: _____

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
	Sex/Gender			
Ethnic Category	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				

Human Subjects Research

Children must be considered for inclusion in all human subject research supported by NIH

Effective for all new applications received after

October 1, 1998

- Child is defined as an individual under age 21
- If children are included, Investigator must address
  - age range
  - expertise of investigative team
  - facilities
  - sufficient numbers

Human Subjects Research

If children are not included, must justify exclusion

- Policy http://grants.nih.gov/grants/funding/children/children.htm

- PHS 398 Supplemental Inst for HS p20
- http://www.niaid.nih.gov/daids/rfa/network06/ctu_rfa_instructions.htm